DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 18,2014

Asante Solutions, Inc.
Edward J. Sinclair
Vice President, Regulatory and Quality Affairs
352 East Java Drive
Sunnyvale, California 94089

Re: K142619
Trade/Device Name: Snap Insulin Pump System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: November 20, 2014
Received: November 21, 2014

Dear Mr. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142619

Device Name
Asante Snap™ Insulin Pump System

Indications for Use *(Describe)*
The Asante Snap Insulin Pump System is indicated for continuous, subcutaneous delivery of insulin at programmable basal and bolus rates for the management of diabetes mellitus in adult patients requiring insulin.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary K142619

Submitter Information

Company: Asante Solutions
352 East Java Drive
Sunnyvale, CA 94089
(408) 716-5600

Edward J. Sinclair
Vice President, Regulatory and Quality Affairs

Date Prepared: December 18, 2014

Device Name and Classification

Common Name:	Insulin Infusion Pump
Proprietary Name:	Snap™ Insulin Pump System
Classification Name:	Pump, Infusion, Insulin
Product Code:	LZG
Regulation Number:	880.5725
Class:	II

Predicate Device

Asante Pearl Diabetes Management System (K122483)

Intended Use

The Snap Insulin Pump System is intended for continuous, subcutaneous delivery of insulin at programmable basal and bolus rates for the management of diabetes mellitus in adult patients requiring insulin.

Device Description

The Snap™ Insulin Pump System is a wearable, continuous, programmable insulin delivery system. It is a portable, battery-powered system capable of delivering insulin at fixed and variable rates. The Snap system consists of the following components and accessories:

1. a software-controlled, programmable, reusable Controller module;
2. a single-use, disposable Pump Body;
3. an Unomedical Asante Comfort™ or Asante Conset™ Infusion Set (K120872), or an equivalently FDA-cleared infusion set with Luer fitting using the Asante sterile, single-use disposable Infusion Set Adapter; and
4. accessories, including the AsanteSync™ download cradle with USB cable, and a fabric Case and plastic Clip that provide a means of attaching the Snap system to the user's belt or other clothing.

The Controller module has a user interface to program delivery parameters for basal and bolus insulin delivery and the Pump Body provides the drive mechanism and battery power and holds the pre-filled insulin cartridges. The user obtains Eli Lilly Humalog fast-acting U100 insulin from their pharmacy and inserts the pre-filled glass cartridge into the Asante Pump Body. The Pump Body is connected to the Controller module and either (a) an Unomedical Asante Comfort or Asante Conset infusion set with proprietary connector, or (b) an Asante Infusion Set Adapter with Luer fitting that connects to commercially available Luered infusion sets to allow delivery of insulin for the management of diabetes.

Summary of Technological Characteristics

The Snap Insulin Pump System has the same technological characteristics as the predicate device. The system uses existing established and unchanged technology and materials, relative to the previously cleared device. The system employs the same drive mechanism as that of the cleared Pearl System (#K122483) to apply controlled and accurate force to move the plunger in the insulin cartridge.

Summary of Changes

The following changes have been made:

- Product trade name change from *Pearl Diabetes Management System* to *Snap Insulin Pump System*
- Component substitutions in the Controller module to address discontinued parts from the respective manufacturer

- Component additions to the Controller module for added electrical protection during assembly
- Increase in the water ingress rating of the Pump Body from IPX5 to IPX7
- Addition of a fabric case, plastic clip and download accessories
- Minor user interface improvements
- Other minor software changes to accommodate componement substitutions, software anomaly resolution and improvements

Performance Testing

Asante completed the appropriate verification and validation activities required by the *Guidance of Industry and FDA Staff – Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions Draft Guidance* and other guidance, as applicable. The system has been verified for performance and functionality to provide assurance that the device modifications have been designed and tested to assure conformance to the requirements for its intended use, based on an evaluation of risks for the type of change involved. All the changes made to the device were assessed to make sure all the risks were sufficiently mitigated and that no new risks were introduced as a result of these modifications.

The following performance and safety testing has confirmed that the proposed device is substantially equivalent to the predicate device:

- **Risk Analysis;** Identification of the hazards associated with the modified device in order to evaluate, estimate and control the associated risks was performed in accordance with ANSI/AAMI/ISO 14971 *Application of risk analysis to medical devices*.
- **Physical characteristics.**
- **Software;** documentation was prepared and submitted for a “major” Level of Concern device in accordance with FDA’s *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* Device software was verified and validated according to IEC 62304:2006 *Medical device software – Software life cycle processes* and FDA’s *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*.
- **Electrical Safety;** the modified Snap Insulin Pump System has been tested and successfully passed all of the relevant sections of the following standards:
    - IEC 60601-1 Medical electrical equipment -- Part 1: *General requirements for safety*.
    - IEC 60601-1-2 *General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests*.

- IEC 60601-2-24 Medical electrical equipment - Part 2-24: *Particular requirements for the basic safety and essential performance of infusion pumps and controllers*.

- **Water Ingress:** the modified Snap Insulin Pump System was tested for the protection of the equipment inside the Controller and Pump Body enclosures against harmful effects due to the ingress of water, in accordance with IEC 60529 *Degrees of protection provided by enclosures (IP Code)*.
- **Electromagnetic Interference;** the modified device has been tested and successfully passed all of the relevant sections of the following standards:
  - IEC 61000-4-2, Electromagnetic Compatibility (EMC) – Part 4-2: *Testing and measurement techniques – Electrostatic discharge immunity test*.
  - IEC 61000-4-3, Electromagnetic Compatibility (EMC) – Part 4-3: *Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*.
  - IEC 61000-4-8, Electromagnetic Compatibility (EMC) – Part 4-8: *Testing and measurement techniques – Power frequency magnetic field test*.

All testing met the acceptance criteria.

Conclusion From Data

Performance testing on the modified device demonstrated that the Snap Insulin Pump System performs reliably and delivers insulin as intended through the infusion sets, and is as safe and as effective as the predicate. Design verification testing confirmed that no new questions of safety or effectiveness were identified during device testing of the modified device.

Based upon the successful safety and performance tests and the similarities to predicate device, the subject Snap Insulin Pump System is substantially equivalent to the predicate Pearl Diabetes Management System in design, features, performance, fundamental scientific technology, and indications for use.